

"Express Mail" mailing label number EL 835293187 US

Date of Deposit October 6, 2003

Our Case No.: 11509/20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Donn M. Dennis, et al.

Serial No.: Unassigned

Filing Date:

For: NOVEL MICROEMULSION AND  
MICELLE SYSTEMS FOR  
SOLUBILIZING DRUGS

Examiner: Unknown

Group Art Unit No.:

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
Alexandria, VA 22313-1450

Dear Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed below and on the attached Form PTO-1449 be considered by the Examiner and made of record. This application is a continuation application of U.S. Serial No. 09/924,290, filed August 8, 2001, which is a continuation-in-part of U.S. Patent Application Serial Number 09/630,237, filed August 1, 2000. These prior applications are relied upon for an earlier filing dated under 35 U.S.C. § 120. The references listed below and on PTO Form 1449 were cited submitted to, or cited by, the Office in connection with prosecution of U.S. Application Serial Nos. 09/924,290 and 09/630,237, and therefore, pursuant to 37 C.F.R. § 1.98(d), copies of the listed documents are not enclosed.

The references now cited are the following:

U.S. Patent Documents:

|              |                |
|--------------|----------------|
| 5,478,860    | J. Wheeler     |
| 5,560,931    | W. Eickhoff    |
| 5,637,625    | D. Haynes      |
| 5,726,164    | H. Weder       |
| 5,858,410    | Muller, et al. |
| 5,908,619    | M. Scholz      |
| 5,908,825    | Fasano, et al. |
| 5,908,869    | C. Jones       |
| 5,916,596    | N. Desai       |
| 5,952,004 A  | Rudnic, et al. |
| 6,197,323 B1 | Georgieff      |
| 5,925,684    | Schweikert     |
| 5,750,142    | Friedman       |
| 6,451,339 B1 | Patel, et al.  |

Foreign Patent Documents:

PCT/IB 96/00868

PCT/US 93/09916

In accordance with 37 C.F.R. § 1.97(g),(h), this Information Disclosure Statement is not to be construed as a representation that a search has been made and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

This Information Disclosure Statement is being filed prior to the receipt of the first Official Action reflecting an examination on the merits and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with filing of this Information Disclosure Statement, however, should any

fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these material, the Commissioner is hereby authorized to deduct said fees from Brinks Hofer Gilson & Lione Deposit Account No. 23-1925. A duplicate copy of this document is enclosed.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,

October 6<sup>th</sup>, 2003 -

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| FORM PTO-1449  | SERIAL NO.<br>Unassigned             | CASE NO.<br>11509/20 |
| <b>LIST OF PATENTS AND PUBLICATIONS FOR<br/>APPLICANT'S INFORMATION DISCLOSURE<br/>STATEMENT</b> | FILING DATE                          | GROUP ART UNIT       |
| (use several sheets if necessary)  | APPLICANT(S): Donn M. Dennis, et al. |                      |

**REFERENCE DESIGNATION                          U.S. PATENT DOCUMENTS**

| EXAMINER INITIAL | DOCUMENT NUMBER<br><small>Number-Kind Code (if known)</small> | DATE    | NAME           | CLASS/<br>SUBCLASS | FILING DATE |
|------------------|---|---------|----------------|--------------------|-------------|
| A1               | 5,478,860   | 12/1995 | J. Wheeler     |                    |             |
| A2               | 5,560,931   | 10/1996 | W. Eickhoff    |                    |             |
| A3               | 5,637,625   | 06/1997 | D. Haynes      |                    |             |
| A4               | 5,726,164   | 03/1998 | H. Weder       |                    |             |
| A5               | 5,858,410   | 01/1999 | Muller, et al. |                    |             |
| A6               | 5,908,619   | 06/1999 | M. Scholz      |                    |             |
| A7               | 5,908,825   | 06/1999 | Fasano, et al. |                    |             |
| A8               | 5,908,869   | 06/1999 | C. Jones       |                    |             |
| A9               | 5,916,596   | 06/1999 | N. Desai       |                    |             |
| A10              | 5,952,004 A   | 09/1999 | Rudnic, et al. |                    |             |
| A11              | 6,197,323 B1  | 03/2001 | Georgieff      |                    |             |
| A12              | 5,925,684   |         | Schweikert     |                    |             |
| A13              | 5,750,142   |         | Friedman       |                    |             |
| A14              | 6,451,339 B1  | 09/2002 | Patel, et al.  |                    |             |

**FOREIGN PATENT DOCUMENTS**

| EXAMINER INITIAL | DOCUMENT NUMBER<br><small>Number-Kind Code (if known)</small> | DATE | COUNTRY | CLASS/<br>SUBCLASS | TRANSLATION<br>YES OR NO |
|------------------|---|------|---------|--------------------|--------------------------|
| A15              | PCT/IB 96/00868   |      | WO      |                    |                          |
| A16              | PCT/US 93/09916   |      | WO      |                    |                          |
|                  |   |      |         |                    |                          |
|                  |   |      |         |                    |                          |
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|                  |   |      |         |                    |                          |

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|-------------------------|--|--|
| <b>EXAMINER INITIAL</b> | <b>OTHER ART – NON PATENT LITERATURE DOCUMENTS</b><br><small>(Include name of author, title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date page(s), volume-issue number(s), publisher, city and/or country where published.)</small> |  |
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|-----------------|------------------------|
| <b>EXAMINER</b> | <b>DATE CONSIDERED</b> |
|-----------------|------------------------|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.